

LUD 5664 (10017134)

**REMARKS**

Claims 33-54 replace previously pending claims 1-12 and 23-32.

The Examiner asserts that applicants' explanations of why they are entitled to priority is not adequate.

First of all, applicants have pointed to commonality of subject matter. Example 21 in the present application is also presented in Serial No. 09/354,243. The example deals with the stimulation of STAT3.

With respect to renaming, "IL-TIF," IL-21" and "IL-22" are given as synonyms, i.e., two or more terms which mean the same thing. Hence, IL-22 is IL-21 is IL-TIF. Further, if the sequence listings, including AF279437, and NM\_020525 are perused, they will be seen to be identical to what is claimed.

Contrary to the Examiner's statement, a detailed explanation was provided. If the Examiner wants something specific, then he should so state. The terms IL-TIF, IL-21 and IL-22 are interchangeable. Applicants have priority via the continuity with the examples – a fact ignored by the Examiner. The reference is proper, the priority claim is proper, and the Examiner should reassess his position and either withdraw the objection, or state the issue clearly for purposes of petition.

The Examiner has rejected all claims under 35 USC § 112, stating that

"the specification while enabling for an in vitro method of stimulating expression of STAT3 and STAT1 comprising contacting a hepatoma cell capable of expression with an amount of human IL-TIF/IL-21 encoded by SEQ. ID. NOS: 24/25;

while enabling for an in vitro method of stimulating expression of STAT3 and STAT5 comprising contacting a cell selected from the group of mesangial neuronal melanoma and hepatoma cells capable of such expression with an amount of mouse IL-TIF/IL-21 encoded by SEQ ID NOS 7/9"

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does not enable the broad claims.

New claim 33 et seq refer to stimulating STAT1 or STAT3, in hepatoma with human IL-TIF/IL-21, or stimulating STAT3 or STAT5, in mesangial, neuronal, melanoma or hepatoma cells with murine IL-TIF/IL-21.

With respect to point "A" of the rejection, the issues relating to different animal types are moot. SEQ ID NOS: 7,8 & 9 & 42 are murine sequences (nucleotide) SEQ. ID. NOS: 25 and 26 (NOT 24 and 25) are human sequences (nucleotide) SEQ ID NOS: 40 and 41 are murine protein sequences. SEQ ID NO: 43 is a human protein sequence. Hence, the sequences recited in the claims differ from those recited in the office action.

With respect to what is allegedly not disclosed, applicants disagree.

The Examiner states that "Applicant has not provided sufficient biochemical information (e.g. molecular weight, amino acid composition N-terminal sequence, etc.)." This statement is clearly contrary to what the Examiner agrees applicant disclose, which includes molecular weight, amino acid sequences, including N-termini, and which de facto include amino acid compositions.

The Examiner continues to rely on non-prior art materials, i.e., Dumoutier, et al, PNAS 97:10144-10149. The point for which their non prior art is relied upon, however, is irrelevant to what is claimed, because stimulation of expression for the Examiner has agreed that STAT1, STAT3 and STAT5 are enablers, and this is what is claimed.

The ability to determine whether or not a molecule functions as claimed is provided by the specification. As the Examiner fully acknowledges, one can determine whether the expression of certain STATs is stimulated, in vitro, and determine it easily. If the molecule in question does do so, and satisfies the physical criteria for IL-22/IL-TIF/IL-21 given in the specification, then it falls within the claims. If it doesn't, it does not.

The fact that experimentation is required to determine if a molecule satisfies the claims does not mean the claims are not enabled. The issue is: is the experimentation

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undue? Since applicants have provided a detailed road map that is readily understandable to one of ordinary skill in the art, it cannot be said that the claims are not enabled.

With respect to the Examiner's position on alleged lack of enablement for in vivo efficacy, the Examiner has referenced general statements and cited to Ex parte Aggarwal which is not relevant.

In Aggarwal, the Examiner provided evidence of prior art showing that there was "considerable doubt" as to the assertion made in the claims. Aggarwal at 1338. No such evidence has been "supplied here. With respect to the combined reliance on non-prior art Dumoutier, it is again pointed out that the claims recite what the Examiner agrees is enabled, i.e., the stimulation of expression of STATS 1 and 3, or STATS 3 and 5. Hence, the Examiner's position cannot be maintained. It certainly cannot be maintained with respect to claims 34, 38-40, 42, 45, 46, 48, 51, 52, + 54, all of which recite in vitro use.

With respect to the Examiner's argument at point 5, this is not understood. If the term used has a clearly defined meaning in the art – as the Examiner admits – then why is it insufficient to recite this in the claims?


With respect to the Ebert reference, applicants find no teaching whatsoever of the use of IL-22/IL-21/IL-TIF with the recited cell types. Far anticipation to be, each facet of what is claimed must be taught, by the reference. The failure of Ebert to do so precludes a rejection.

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Allowance of this application is helieved proper, and is urged.

Respectfully submitted,

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